UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION THIS DOCUMENT RELATES TO: *Moore et al v. Purdue Pharma L.P. et al.*, No. 1:18-op-46305-DAP	MDL No. 2804 Case No. 1:17-md-2804 Judge Dan Aaron Polster

DEFENDANT MCKESSON CORPORATION'S NOTICE REGARDING POTENTIAL NONPARTY FAULT UNDER W. VA. CODE § 55-7-13d

Defendant McKesson Corporation ("McKesson"), by counsel, hereby submits its notice of nonparty fault pursuant to W. Va. Code § 55-7-13d. West Virginia Code § 55-7-13d(a)(2) states that "[f]ault of a nonparty shall be considered . . . if a defending party gives notice no later than one hundred eighty days after service of process upon said defendant that a nonparty was wholly or partially at fault."[1]

Plaintiff and putative class representative Bobbie Lou Moore[2] seeks to hold Defendants responsible for an opioid epidemic that Defendants, much less any one of them, could not possibly have caused. Wholesale pharmaceutical distributors, such as McKesson, merely distribute prescription medications from various manufacturers to licensed pharmacies. Distributors have no role in manufacturing or promoting opioids to physicians; they have no role in determining how opioids should be or are prescribed; and they have no role in determining how pharmacists dispense opioids. Distributors similarly do not set or enforce the quotas that limit the number of opioids

[1] Given this statutory language, McKesson is filing its Notice at this time in an abundance of caution.

[2] Plaintiff filed this class action complaint as next friend and guardian of Minor R.R.C., and as putative class representative of all others similarly situated. (*See* Compl. ¶¶ 17–20.)

shipped nationally to licensed pharmacies. And distributors have no law enforcement duty or authority over opioids after a licensed pharmacy receives its bulk shipments.

Litigation of Plaintiff's claims, then, necessarily involves all persons and entities who were involved in manufacturing, prescribing, dispensing, regulating, and paying for opioid medications, as well as those involved in the illegal production and sale of heroin and other illegal drugs. To the extent any entity can be held liable for causing the opioid epidemic, fault for the injuries alleged in the Complaint will need to be apportioned among nonparties. *See* W. Va. Code § 55-7-13d(a)(6) ("In all actions involving fault of more than one person, unless otherwise agreed by all parties to the action, the court shall instruct the jury to answer special interrogatories or, if there is no jury, shall make findings, indicating the percentage of the total fault that is allocated to each party and nonparty pursuant to this article.").

This case has been transferred to the Opioid MDL and was not selected as an initial bellwether, so the parties have not begun discovery. Thus, at this time, McKesson cannot specifically identify nonparties that could be at fault for the injuries alleged in Plaintiff's Complaint. McKesson therefore identifies the categories of individuals and entities who may be nonparties at fault based on their legal obligations. This is the "best identification of the nonparty which is possible under the circumstances." W. Va. Code § 55-7-13d(a)(2). McKesson will supplement this notice once the specific identities of nonparties with potential fault are discovered.

I. Pharmacies and Pharmacists

McKesson distributes controlled substances only to pharmacies that hold valid licenses from the Drug Enforcement Administration (the "DEA") and in West Virginia, the Board of Pharmacy (the "WVBOP"). Individual pharmacists working at those pharmacies also must be DEA-registered and licensed by the WVBOP. Pharmacies cannot dispense a controlled substance other than in response

to a valid prescription from a licensed doctor, and pharmacists have a "corresponding responsibility" not to fill a prescription that the pharmacist knows was written for other than a medically necessary purpose.[3]

If putative class members have been harmed as Plaintiff alleges, it would be, in part at least, because pharmacies dispensing controlled substances were not complying with their legal obligations when dispensing those controlled substances. Plaintiff, however, fails to specifically identify any pharmacy or pharmacist that allegedly failed to comply with its legal obligations when dispensing controlled substances. Although placing suspicious orders is not unlawful and suspicious orders do not necessarily indicate unlawful diversion, Plaintiff also fails to specifically identify any pharmacy that placed suspicious orders that McKesson then allegedly failed to identify and report. Once any pharmacies and their pharmacists are shown to have dispensed controlled substances in violation of their legal obligations, McKesson will supplement this notice with their identities.

II. Prescribing Practitioners

Prescribing practitioners must be registered with the DEA and licensed by a State medical board. A prescribing physician can write an opioid prescription only for a medically necessary purpose after examining the patient.[4]

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[3] Although the primary "responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner," DEA regulations place a "corresponding responsibility" on the "pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a); *see also* W. Va. C.S.R. § 15-2-7.4.1 (same). The DEA requires "pharmacists [to] use common sense and professional judgment," which includes paying attention to the "number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment," the number of doctors writing prescriptions, and whether the drugs prescribed have a high rate of abuse. *Ralph J. Bertolino Pharmacy, Inc.*, 55 Fed. Reg. 4,729, 4,730 (DEA Feb. 9, 1990). DEA requires that a pharmacist refuse to dispense when a prescription raises suspicion and its propriety cannot be verified. *Id.*

[4] Federal and state regulations require that prescriptions for controlled substances "be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a); W. Va. C.S.R. § 15-2-7.4.1 (requiring that practitioners "issue a prescription for a controlled substance for a legitimate medical purpose in the usual course of his or her professional practice"). Also, it is unlawful for patients to deceive doctors to obtain opioid prescriptions. *See* W. Va.

If putative class members have been harmed as Plaintiff alleges, it would be, in part at least, because prescribing practitioners wrote prescriptions for controlled substances for other than a medically necessary purpose. Plaintiff, however, fails to specifically identify any prescribing practitioner that allegedly failed to comply with its legal obligations when writing prescriptions for controlled substances. Once any prescribing practitioners are shown to have written prescriptions for controlled substances in violation of their legal obligations, McKesson will supplement this notice with the practitioners' identities.

III. Individuals Involved in Illegal Drug Sales

If putative class members have been harmed as Plaintiff alleges, it may be, in part at least, because individuals have been involved in illegal sales or sharing of opioid medications, heroin, and/or other illegal drugs. Plaintiff, however, fails to identify any individual involved in the illegal distribution of opioids or the distribution of illegal drugs, and, furthermore, it may not be possible to identify all such individuals. To the extent that such individuals are identified in the course of discovery, McKesson will supplement this notice with their identities.

IV. Nonparty Pharmaceutical Manufacturers

To the extent the opioid medications distributed by McKesson to pharmacies were improperly dispensed because of inadequate instructions or warnings, or false or misleading advertising and promotion by the manufacturers, pharmaceutical manufacturers' actions or omissions contributed to the harms alleged by Plaintiff. It is possible that Plaintiff has not named as defendants all pharmaceutical manufacturers whose opioid medications carried inadequate instructions or warnings, or who promoted opioid medication through false or misleading advertising or other forms of

Code § 60A-4-403(a)(3) (making it unlawful to knowingly or intentionally "obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge").

promotion. To the extent that such nonparty pharmaceutical manufacturers are identified, McKesson will supplement this notice with their identities.

V. Nonparty Wholesale Pharmaceutical Distributors

McKesson is only one of many wholesale distributors that distribute medications to pharmacies. To the extent that controlled substances were distributed in violation of regulatory reporting requirements to federal and state enforcement authorities, those controlled substances were distributed, at least in part, by wholesale pharmaceutical distributors other than McKesson. McKesson, however, does not have complete access to the DEA's ARCOS database, which contains the identities of all pharmaceutical distributors that distributed controlled substances. McKesson also does not have access to other evidence of any other entity distributing controlled substances in violation of federal or state regulatory requirements. It is possible that Plaintiff has not named as defendants all wholesale pharmaceutical distributors that have distributed controlled substances in violation of federal or state regulatory requirements. To the extent that any nonparty pharmaceutical distributors that have shipped controlled substances in violation of federal or state regulatory requirements are identified, McKesson will supplement this notice with their identities.

VI. Federal, State, and Local Government Entities

The Food and Drug Administration (the "FDA") comprehensively regulates prescription drugs in the United States. The DEA, through delegated authority, administers and enforces the federal Controlled Substances Act and its implementing regulations, including establishing annual production quotas for schedule II controlled substances, such as opioid medications. The WVBOP administers and enforces the West Virginia Uniform Controlled Substances Act and its implementing regulations. The WVBOP also administers the State's Prescription Drug Monitoring Program to which pharmacies and prescribing practitioners, but not distributors, report and have access. The

West Virginia Board of Medicine, the West Virginia Board of Osteopathic Medicine, the West Virginia Board of Dentistry, and the West Virginia Board of Examiners for Registered Professional Nurses are responsible for licensing and regulating practitioners who prescribe controlled substances to West Virginia residents. The West Virginia State Police, the County Sheriffs' Departments, and the police departments of municipalities are responsible for enforcing the laws related to illegal drug sales. The Bureau for Medical Services ("BMS") of the West Virginia Department of Health and Human Resources administers the West Virginia Medicaid Program "to improve the quality of care and health outcomes for West Virginia Medicaid members by assuring that the medications prescribed for them are appropriate, *medically necessary*, and not likely to result in adverse medical effects" (emphasis added). BMS requires, *inter alia*, that prior authorization be obtained through the Rational Drug Therapy Program (the "RDT") of the WVU School of Pharmacy before opioids prescribed for chronic pain are reimbursable. The West Virginia Public Employees Insurance Agency (the "PEIA") likewise requires prior authorization through the RDT for certain opioid medications before the medications are reimbursable. As the PEIA's website states, "[a]ll prior authorization requests must be reviewed annually." Other federal and state programs that provide reimbursement for opioid medications may similarly seek to ensure the medical necessity of prescription opioids.

The failure of these federal, state, and local government entities, individually and/or collectively, to take timely and effective enforcement action, caused or contributed to the harms alleged by Plaintiff. Accordingly, McKesson identifies any federal, state, or local government entity that failed to take timely and effective enforcement action related to the unlawful manufacture, promotion, sale, dispensing, prescribing, and/or diversion of controlled substances, or related to the

illegal sale of drugs as nonparties at fault.[5] To the extent any such entities are identified during discovery, McKesson will supplement this notice with their identities.

VII. Health Insurers

Health insurers, including private companies as well as Medicare, Medicaid, and the state and federal agencies that administer these and other government programs, including the West Virginia Department of Health and Human Resources and BMS, have historically made prescription coverage decisions, either on their own or in concert with Pharmacy Benefit Managers and drug manufacturers, based on pricing, incentives, and rebates—decisions that may have had the effect of driving patients to opioids and away from abuse-deterrent formula (ADF) opioids and less addictive forms of opiates, as well as other alternative treatments. Health insurers may have therefore made it more difficult for patients to obtain, and/or to obtain coverage for, medications that are less addictive and/or physical therapies that do not have a risk of addiction.

In addition, public and private health insurers may have had access to, or maintained, data reflecting which doctors mis- or over-prescribed opioid medications, but failed to act on that information. Health insurers may also have had access to, or maintained, data reflecting which pharmacies dispensed controlled substances in violation of the pharmacies' legal obligations. As a wholesale distributor with no direct access to patients, and due to the restrictions of the federal Health Insurance Portability and Accountability Act ("HIPAA"), McKesson did not know—and had no ability to know—which practitioner prescribed opioid drugs for which patient, for what medical purpose, with what regularity, or in what amounts. Nor did McKesson know which pharmacy, hospital, or clinic dispensed them.

[5] Governmental entities may be "wholly or partially at fault" under W. Va. Code § 55-7-13d, whether or not they enjoy immunity from suit or otherwise cannot be named as a party defendant.

Accordingly, McKesson identifies public and private health insurers as nonparties at fault. Plaintiff, however, fails to identify which insurers employed reimbursement policies and practices that may have had the effect of driving up opioid use, or which insurers may have had access to relevant patient and pharmacy data. To the extent that such insurers are identified during discovery, McKesson will supplement this notice with their identities.

VIII. Pharmacy Benefit Managers

Pharmacy Benefit Managers ("PBMs") are brokers between payers representing patients, drug manufacturers, and retailers. In this role, PBMs influence the drug products used and prescribed most frequently. PBMs control the dissemination of opioids and other non-opioid alternatives through their determination of rebates and incentives for specific drugs, acting in concert with manufacturers and pharmacies. With this market control, PBMs are able to use the health insurance company's formulary to ensure that health insurers select only the drugs in favor with the PBMs for insurance coverage. Where the PBMs influence coverages, specific drugs not covered may not enter the marketplace and others that are covered may be overprescribed. As a result, PBMs may have made it more difficult for patients to obtain, and/or to obtain coverage for, medications that are potentially less addictive. The PBMs' formulary and pricing strategies may have driven patients to opioids and away from abuse-deterrent formula (ADF) opioids and less addictive forms of opiates.

Additionally, PBMs may have had access to, or maintained, data reflecting which doctors mis- or over-prescribed opioid medications, but failed to act on that information. PBMs may also have had access to, or maintained, data reflecting which pharmacies dispensed controlled substances in violation of the pharmacies' legal obligations. As a wholesale distributor with no direct access to patients, and due to the restrictions of the federal Health Insurance Portability and Accountability Act ("HIPAA"), McKesson did not know—and had no ability to know—which practitioner prescribed

opioid drugs for which patient, for what medical purpose, with what regularity, or in what amounts. Nor did McKesson know which pharmacy, hospital, or clinic dispensed them.

Accordingly, McKesson identifies PBMs as nonparties at fault. Plaintiff, however, fails to identify which PBMs employed policies and practices that may have had the effect of driving up opioid use, or which PBMs may have had access to relevant patient and pharmacy data. To the extent that such PBMs are identified during discovery, McKesson will supplement this notice with their identities.

Reservation of Right to Amend After Discovery

Discovery has not yet begun in this case. McKesson therefore reserves its right to amend this notice to add any nonparties that may have whole or partial fault for putative class members' alleged harms and supplement this list with the names and addresses of the nonparties at fault once discovery reveals the specific identities of those parties.

Dated this the 13th day of February, 2019.

McKESSON CORPORATION,
By Counsel

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CERTIFICATE OF SERVICE

I, Geoffrey Hobart, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

/s/ Geoffrey E. Hobart

Geoffrey E. Hobart